

“Dirty Dozen 2006”

The following are the most frequently cited pharmacy inspection deficiencies

1. § 54.1-3404 & 18 VAC 110-20-240

Biennial inventory cannot be located or is not taken every two years. Biennial inventory is not signed, dated, or does not indicate if taken at the opening or close of business.

The Code states that “Every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory.” “After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.” “All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded.” The regulations state that “all inventories...shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business”. Remember that if your pharmacy is open 24 hours the regulation requires “A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

Records of receipt of drugs do not indicate the actual date of receipt of the drugs.

The Code states that “The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture.”

2. 18 VAC 110-20-355

Filled prescriptions that are returned to stock are not labeled with an appropriate expiration date.

Guidance Document 110-16 Returning Drugs to Stock from "Will-Call" states “A pharmacy may return a dispensed drug to stock from will-call provided the drug is treated as a repackaged drug for use by that pharmacy only in accordance with 18 VAC 110-20-355. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer’s container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. The restocked drug should be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it will be removed from stock and destroyed or otherwise disposed of in accordance with regulations. If there is no lot number on the label of a drug returned to stock or on the prescription records which can be cross referenced from the prescription label, the drug will be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with regulations.

3. § 54.1-3410

The full name of the physician's agent is not recorded on the hard copy prescription.

The Code states that “Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.”

Labels and stickers are placed on the face of the hard copy prescription obscuring the required information.

The Code states that “If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed”. Labels and stickers may not be placed on the prescription in such a way as to obscure the required information.

4. 18 VAC 110-20-250

Automated data processing records of prescriptions

The regulation states “Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system by either maintaining a log or printout. If a printout is maintained of each day’s prescription dispensing data, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J.H. Smith or John H. Smith). If a bound log book, or separate file is maintained rather than a printout, each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information entered into the computer that day has been reviewed by him and is correct as shown”.

5. **18 VAC 110-20-150**

The pharmacy does not have hot and/or cold running water. The refrigerator used for drug storage does not have a monitoring thermometer or is not maintained at the proper temperature.

6. **§ 54.1-3468**

The paraphernalia sales record is missing required information such as date of dispensing, name and item, price, name and address of person to who dispensed, reason for purchase, and pharmacist's initials.

The Code states that "At the time of dispensing, make and keep a record showing the date of dispensing, the name and quantity of the device, item or substance, the price at which it was sold, the name and address of the person to whom the device, item or substance was dispensed, the reason for its purchase and enter his initials thereon."

7. **§§ 54.1-3314 & 54.1-3430**

Pharmacy permit and pharmacist license are not displayed "conspicuously" in a manner that is easily readable to public.

The Code states that "Every person licensed to practice as a pharmacist must at all times display his license conspicuously in the place in which he regularly practices". "Permits issued under the provisions of this chapter shall be displayed in a conspicuous place in the factory or other place of business for which issued."

8. **18 VAC 110-20-200**

Expired drugs are found in the stock of drugs used for dispensing.

The regulation states that "any drug which has exceeded the expiration date shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal".

9. **18VAC110-20-111**

Pharmacy Technicians

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians for no more than nine months without that person becoming registered as a pharmacy technician with the board. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program.

10. **18 VAC 110-20-190**

Prescription department enclosure is not of sufficient height to prevent a person from reaching over to gain access to drugs. Doors to the prescription department are broken or are not able to be locked to prevent unauthorized entry.

The regulations state that "The enclosure shall be constructed in such a manner that it protects the controlled drug stock from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty". "The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the drugs." Doors to the area must have locking devices which will prevent unauthorized entry in the absence of the pharmacist."

11. **18 VAC 110-20-255**

Other Dispensing Records

Pursuant to §54.1-3412 of the Code of Virginia, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing

12. **18 VAC 110-20-160**

Sanitary Conditions

A. The entire area of any place bearing the name of a pharmacy shall be maintained in a clean and sanitary manner and in good repair and order. B. Adequate trash disposal facilities and receptacles shall be available.